Increasing vaccine availability in developing countries

Partnership models for PPPs

International Vaccine Technology Workshop



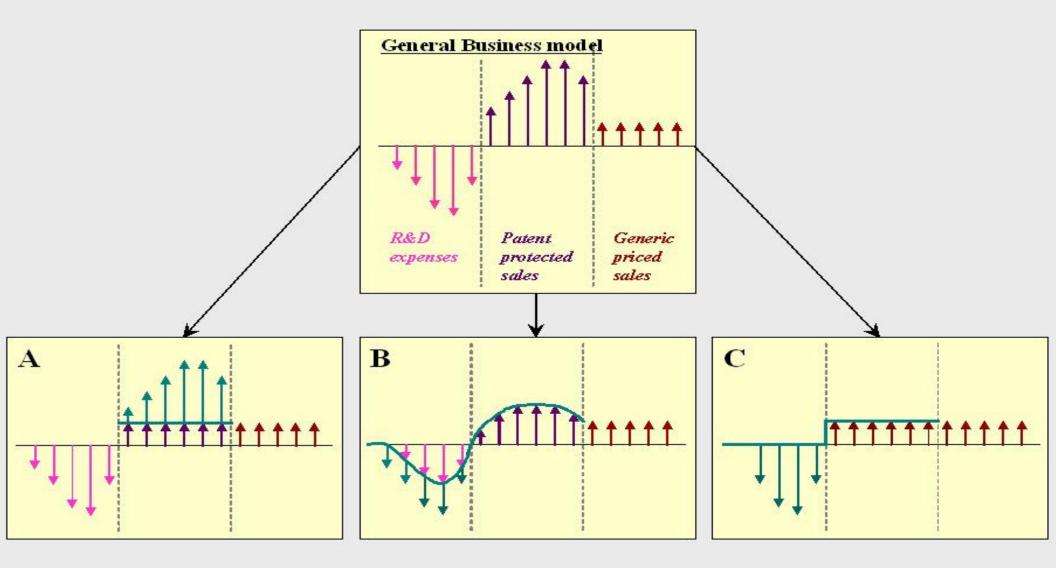
September 17-18, 2010

Hyderabad, India

Marie-Paule Kieny



Models of Commercial and NFP collaboration



Public-private partnership - A

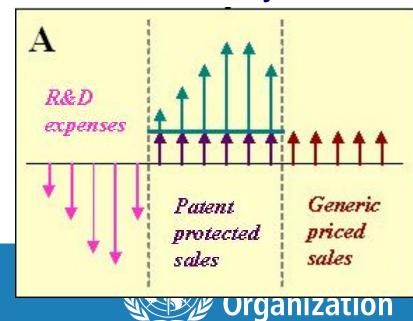
- E.g the Pneumo AMC model
- The public sector subsidizes sales during the first vaccine introduction phase, in exchange of guaranties on "tail price"

GSK-Bio and Pfizer contracted for 30 million doses/year

each for 10 years

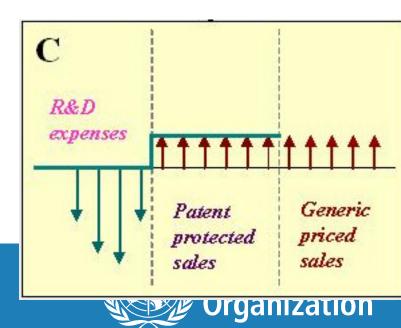
No DCVM eligible before 2015?

Expensive model



Public-private partnership - C

- E.g. the Meningitis Vaccine Project (MVP) model
- The public sector covers all development costs and organises technology transfer to one DCMN (SII)
- Pricing agreement including in the partnership contract guarantee low and sustainable prices from the onset
- Open to only one DCVM
- Associated with some vaccine security risks as for any monopoly



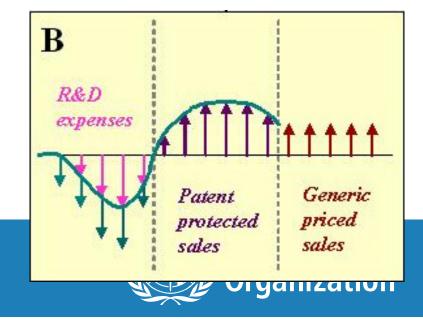
Public-private partnership - B

 E.g. the WHO influenza vaccine production technology transfer model

 The public sector finances part of the development costs, and facilitates technology transfer and access to new technology, in exchange of price concession for the public sector of developing countries, starting as soon as the

vaccine is introduced

Open to multiple DCVM



Extension of the B model through a Center of Excellence ("Hub") Model

Major challenges encountered during the first phase of the WHO influenza vaccine production technology transfer programme

- Finding willing technology providers proved very difficult
- Limited human resources at new manufacturers' site

Establishment of a Center of Excellence as a "technology hub" to serve as technology provider

- A technology platform for transferring a robust production process with relevant documentation (SOPs, Batch Process Records, validation procedures, analytical methods and release criteria)
- A technology package transferable to interested developing country vaccine manufacturers, upon request (and possibly against fees), without IPR hurdles



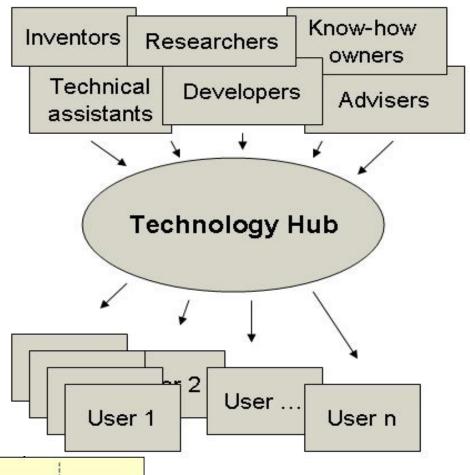
Principle of the Center of Excellence ("Hub") Model

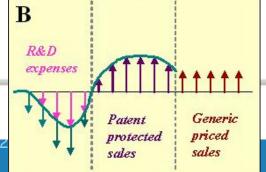
Technology Owner:

Inventor & developer or Owner of rights & know-how

User:

Use & Commercialization entity or Further developer







Partnership with WHO to establish a NVI Center of Excellence and training for Influenza vaccine



The Netherlands Vaccine Institute

Jnique Values:

- Over 100 years vaccinology know-how
- Independent
- Production infrastructure covering entire value chain

Access to:

- Technical advice
- Process and production technology
- Documentation
- Assays
- (Pre)clinical support

Three Training Courses since 2009

- 10 bench places/course
- Based on a two volume Course Manual
- Hands-on demonstration of one dedicated "training" run

(presented in more details by Dr Claire Boog)

Achievements of the Center of Excellence: 2008-2010

- The Technology transfer & training center established at the NVI campus in Bilthoven, the Netherlands is fully operational.
- NVI through contractual agreements is engaged in bi-lateral technology transfer projects with developing country vaccine manufacturers (Vacsera, Egypt and IVAC, Vietnam - other agreements pending).
- (More information on the technology "hub" in Claire Boog's presentation)



























Discussion

- Partnerships are all unique
- Technology transfer is traditionally a business to business approach, starting from labelling and packaging through fill/finish to eventually encompass bulk production, but other models can be envisaged
- Success depends on the engagement of both the technology provider and the recipient, with mutual respect and trust
- Establishment of a centre of excellence can be an asset when a particular technology is to be transferred to multiple manufacturers
- Attention must be given to parallel strengthening of the corresponding National Regulatory Authorities

